DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

DEC 1 2004

Dennis J. Allingham
President and CEO
Lifecore Biomedical, Inc.
3515 Lyman Boulevard
Chaska, Miinnesota 55318-3051

Dear Mr. Allingham:

This is a partial reply to your October 29, 2004, letter to Mr. Paul Tilton in response to our Warning Letter dated October 8, 2004. We have considered your request that the Food and Drug Administration (FDA) post your response letter on its web site. We agree to post your response without the attachment (as you requested) on our web site.

Your letter raises numerous issues regarding the Warning Letter and FDA actions. We plan to issue a complete response addressing those issues in a reply to your response to the Warning Letter. In this partial reply, we note that we disagree with the characterizations in your October 29, 2004, letter regarding FDA's actions in connection with the request for a meeting and the teleconference held on September 2, 2004.

The letter states that FDA "refused" to provide an opportunity for an in-person meeting to discuss FDA expectations for medical device reporting (MDR). We disagree. We proposed a teleconference to facilitate full participation in the meeting by the Center and the FDA Minneapolis District Office. You appeared to agree with this decision at the time. We believe that the agency's use of a teleconference for the meeting in this situation was appropriate, and you have not suggested any reason why an in-person conference would have led to a different result.

The letter also states that "FDA informed Lifecore that the agency would not provide Lifecore with any guidance on MDR reporting." At the start of the conference, we informed your representatives that we intended it to be a "listening" meeting. We advised them it was their opportunity to present and discuss their MDR issues. We also informed them that the one hour time frame would not provide adequate time to discuss each of the complaints, on a one by one basis.

As it turned out, we spent the better part of the allotted time discussing the MDR requirements with your representatives and discussing, extensively, a couple of the individual complaints cited in the FDA 483, as representative examples. Therefore, we believe that we did provide Lifecore's representatives with additional information on MDR requirements as requested.

We will respond to the other issues raised in your letter as soon as possible.

Sincerely yours,

Betty W. Collins

Betty W. Collins
Director
Division of Enforcement A
Office of Compliance
Center for Devices and
Radiological Health